

84. A nanoparticulate aerosol composition for use in a propellant-based pMDI comprising:

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- (a) a nanoparticulate poorly soluble crystalline drug, wherein the drug has a surface modifier adsorbed on the surface thereof, and the drug has an effective average particle size of less than about 1000 nm,
 - (b) essentially each droplet of the aerosol comprises at least one nanoparticulate drug particle, wherein the droplets of the aerosol generated by the pMDI have a diameter of less than or equal to about 100 microns, and
 - (c) a non-aqueous propellant.

85. The aerosol composition of claim 84, wherein the propellant is a non-CFC propellant.

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86. The aerosol composition of claim 84, wherein the drug is selected from the group consisting of proteins, peptides, bronchodilators, corticosteroids, elastase inhibitors, analgesics, anti-fungals, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, an analgesic, and a cardiovascular agent.

87. The aerosol composition of claim 84, wherein the nanoparticulate drug particles have an effective average particle size of less than about 400 nm.

88. The aerosol composition of claim 87, wherein the nanoparticulate drug particles have an effective average particle size of less than about 300 nm.

89. The aerosol composition of claim 88, wherein the nanoparticulate drug particles have an effective average particle size of less than about 250 nm.

90. The aerosol composition of claim 89, wherein the nanoparticulate drug particles have an effective average particle size of less than about 100 nm.

91. The aerosol composition of claim 90, wherein the nanoparticulate drug particles have an effective average particle size of less than about 50 nm.

92. The aerosol composition of claim 84, wherein the aerosol comprises a concentration of a drug in an amount of from about 0.05 mg/mL up to about 600 mg/mL.

B) 93. The aerosol composition of claim 84, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/mL or more, about 100 mg/mL or more, about 200 mg/mL or more, about 400 mg/mL or more, and about 600 mg/mL.

94. The aerosol composition of claim 84, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 2 to about 10 microns.

95. The aerosol composition of claim 90, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of from about 2 to about 6 microns.

96. The aerosol composition of claim 84, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of less than about 2 microns.

97. The aerosol composition of claim 84, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 5 to about 100 microns.

98. The aerosol composition of claim 97, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 30 to about 60 microns.

99. The aerosol composition of claim 84, wherein at least 70% of the drug particles have a particle size of less than about 1000 nm.

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100. The aerosol composition of claim 84, wherein at least 90% of the drug particles have a particle size of less than about 1000 nm.

101. A method of administering the aerosol of claim 84 to a patient, wherein the aerosol comprises drug at a concentration of 10 mg/g or greater, and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.

102. A method of making an aerosol composition of nanoparticulate drug particles for use in a propellant-based pMDI, wherein said nanoparticulate drug particles comprise a poorly soluble drug, have an effective average particle size of less than about 1000 nm, and have a non-crosslinked surface modifier adsorbed on the surface thereof; wherein the method comprises:

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- (a) providing a dispersion of said nanoparticulate drug particles in a liquid propellant; and
 - (b) forming an aerosol comprising liquid droplets of said dispersion, wherein:
 - (i) essentially each droplet of the aerosol comprises at least one nanoparticulate poorly soluble drug particle and at least one surface modifier adsorbed to the surface of the drug particle, and
 - (ii) the liquid droplets forming the aerosol have a mass mean aerodynamic diameter of less than about 100 microns.

103. The method of claim 102, wherein the drug is selected from the group consisting of proteins, peptides, bronchodilators, corticosteroids, elastase inhibitors, analgesics, anti-fungals, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, an analgesic, and a cardiovascular agent.

104. The method of claim 102, wherein the nanoparticulate drug particles have an effective average particle size of less than about 400 nm.

105. The method of claim 104, wherein the nanoparticulate drug particles have an effective average particle size of less than about 300 nm.

106. The method of claim 105, wherein the nanoparticulate drug particles have an effective average particle size of less than about 250 nm.

107. The method of claim 106, wherein the nanoparticulate drug particles have an effective average particle size of less than about 100 nm.

108. The method of claim 107, wherein the nanoparticulate drug particles have an effective average particle size of less than about 50 nm.

109. The method of claim 102, wherein the aerosol comprises a concentration of a drug in an amount of from about 0.05 mg/mL up to about 600 mg/mL.

B 110. The method of claim 109, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/mL or more, about 100 mg/mL or more, about 200 mg/mL or more, about 400 mg/mL or more, and about 600 mg/mL.

111. The method of claim 102, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 2 to about 10 microns.

112. The method of claim 102, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of from about 2 to about 6 microns.

113. The method of claim 102, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of less than about 2 microns.